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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/517,805

12/05/2005

Ernesto Menta

M500-F112

8932

500 7590 05/02/2008

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EXAMINER

DENTZ, BERNARD I

ART UNIT

PAPER NUMBER

1625

MAIL DATE

DELIVERY MODE

05/02/2008

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/517,805	MENTA ET AL.	
	Examiner	Art Unit	
	Bernard Dentz	1625	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 23 January 2008.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 11 and 15-21 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 11 and 15-21 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>1-23-08</u> . | 6) <input type="checkbox"/> Other: _____ |

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35 U.S.C. 101 reads as follows:

Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

The claimed invention lacks patentable utility. What is the utility of the invention.? What is the locus in which a cell is treated.? Is it in a the body of an animal? Is it a plant cell? If it is to treat a specific disease it would have a utility. Here the utility is in doubt. The words of the claim should clearly express the utility.

A claim to a physiological effect of a compound on animal cells is not a specific utility.

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 11and 15-21 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention. The specification provides no enablement for the treating of any condition in animals.The wide variety of compounds are certainly not enabled.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 18-20 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which

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applicant regards as the invention. Claim 17 limits A to thiazolyl wherein the thiazolyl ring is connected to the coumarin ring thru the 2-, 4-, or 5-position. Claim 18 which depends on claim 17 recites values for A which do not meet this definition. See values 4,5,7, 8,9 and 11.

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

Claims 11 and 15-20 are rejected under 35 U.S.C. 102(b) as being anticipated by Chiarino et al, EP 284017 cited by applicants. It discloses the synthesis of various esters, amides and salts of N-[4-(3-coumarin-yl)-2-thiazolyl] oxamic acid. The compounds are useful in treating arthritis which is known to be treatable with VEGF inhibitors. See below.

Note that the A can be substituted by carbonylamino groups.

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 11 and 15-21 are rejected under 35 U.S.C. 103(a) as being unpatentable over Walsh et al in view of Chiarino et al, EP 284017 both cited by applicants. The former teaches that angiogenesis which is stimulated by VEGF contributes to inflammatory disease and that angiogenesis inhibitors may reduce inflammation and may also help to restore appropriate tissue structure and function.

The latter discloses that 3-thiazolyl coumarins are useful in treating inflammatory conditions ,such as arthritis.

Thus the instant method of inhibiting VEGF production using a 3- thiazolyl coumarin within the scope of the patent would have been obvious to one of ordinary skill in the art.

Claims 11,15,16 and 18-20 are rejected under 35 U.S.C. 102(a) as being anticipated by Srimanth et al. It discloses the synthesis of some 3- (bicyclo- and tricyclo-heteroaryl)-coumarins all of which contain a thiazolo moiety . The compounds showed very good activity against different tumor cell lines.

Compounds 2a-2h of the reference contain the moiety that applicants name benzo[d]imidazo[2,1-b]thiazol-2-yl. The reference uses imidazo[2,1-b]benzothiazole to refer to this ring system. See 2-(2H-1-benzopyran-2-one-3-yl)imidazo[2,1-b]benzothiazoles at p. 390 bottom of col. 2.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Bernard Dentz whose telephone number is 571-272-0683. The examiner can normally be reached on Mon-Fri from 8 to 4:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Janet Andres, can be reached on 571 272-0867. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

4-23-2008

/ Bernard Dentz/

Primary Examiner, Art Unit 1625